



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/768,565

01/29/2004

Karla Weaver

10123/00801

6338

7590 09/02/2009
Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BOSTON SCIENTIFIC SCIMED, INC.

Appeal 2009-003237
Application 10/768,565
Technology Center 3700

Decided: September 02, 2009

Before RICHARD E. SCHAFER, JAMESON LEE, and
MICHAEL P. TIERNEY, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge*.

DECISION ON APPEAL

A. STATEMENT OF THE CASE

This is a decision on appeal by the real party in interest, Boston Scientific Scimed, Inc. (Boston Scientific), under 35 U.S.C. § 134(a) from a

final rejection of claims 1-21. We have jurisdiction under 35 U.S.C. § 6(b).
We affirm-in-part.

References Relied on by the Examiner

Mikhail et al. (Mikhail)	5,707,357	Jan. 13, 1998
--------------------------	-----------	---------------

The Rejections on Appeal

The Examiner rejected claims 1-21 under 35 U.S.C. § 102(b) as anticipated by Mikhail.

The Invention

The invention relates to a pressure actuated valve having a valve membrane with a plurality of slits that open to allow fluid flow in response to pressure on the membrane. (Spec. 2: ¶ 5.)

Independent claim 1 is reproduced below (Claims App'x 12:1-12):

1. A pressure actuated valve for controlling the flow of fluid through a medical device, the valve comprising:

a housing including a lumen extending therethrough; and

a flow control membrane extending across the lumen to control the flow of fluid through the lumen, the membrane including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen and, when not acted upon by a pressure of at least the predetermined magnitude, the slits are maintained closed by a biasing force applied thereto by the membrane to prevent flow through the lumen, wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits.

B. ISSUES

1. Has Boston Scientific shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane that is acted upon by a pressure of at least a threshold magnitude?

2. Has Boston Scientific shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane with slits where a distance between an end portion of a first slit and an end portion of a second slit is a minimum distance between the slits?

3. Has Boston Scientific shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane that is substantially planar?

C. FINDINGS OF FACT

1. Mikhail discloses a catheter having valve 36. (Mikhail 11:11-15.)

2. In Mikhail, valve 36 includes valve member 38 having a plurality of curved openings or slits 76. (*Id.* at 22:38-39.)

3. Mikhail discloses that the slits in the valve membrane are opened to allow the passage of fluid by the manual application of radially inward squeezing pressure to the sides of the valve. (*Id.* at 11:15-18; 22:38-62.)

4. Mikhail's Figure 16 shows an embodiment of Mikhail's valve 36 in which openings or slits 76 of valve member 38 have been forced open due to the insertion of stent tube 88. (*Id.* at 23:54-65.)

5. Mikhail equates the term "planar" with the terms "generally flat" and "completely flat." (*Id.* at 24: ll. 46 and 56.)

6. Mikhail discloses member 38 as being arcuate or dome shaped.
(*Id.* at 11:12-13; 23:27-28.)

D. PRINCIPLES OF LAW

A prior art reference anticipates a claim if it discloses every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

During examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). The broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an amendment. *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

Absent claim language carrying a narrow meaning, a claim should only be limited based on the specification and prosecution history when those sources expressly disclaim the broader definition. *In re Bigio*, 381 F.3d at 1325.

A prior art reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect. *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985); *see also In re Bode*, 550 F.2d 656, 661 (CCPA 1977).

E. ANALYSIS

The Examiner rejected claims 1-21 as anticipated by Mikhail.

Claim 1, 10, 17, 20, and 21 are independent claims. Dependent claims 2-9 are argued collectively with independent claim 1. Independent claims 17, 20, and 21 and dependent claims 18 and 19 are asserted by Boston Scientific as being patentable for the same reasons as those urged for claim 1. Claims 1-9 and 17-21 are grouped together and considered in light of the arguments made for claim 1. Claims 10-16 are argued as patentable for reasons that are additional to those advanced for claim 1. Claims 10-16 are thus grouped separately. We focus on the claim limitations that are in dispute.

Claims 1-9 and 17-21

Boston Scientific's first argument centers on the meaning of "pressure" in the context of claim 1's "pressure actuated valve" including a valve membrane that opens when "acted upon by a pressure of at least a threshold magnitude." The Examiner interpreted the term "pressure" as "any type of force exerted upon a surface including a force exerted by fluid and squeezing, etc." (Ans. 3:10-18.) Mikhail discloses that its valve is opened to allow the passage of fluid by the manual application of radially inwardly squeezing pressure to the sides of the valve. (Mikhail 11:15-18; 22:38-62.) The Examiner reasoned that Mikhail's valve is thus a pressure actuated valve because the opening of its valve membrane requires the application of squeezing pressure. (App. Br. 6:14-18.)

Boston Scientific contends that its specification makes clear that a "pressure actuated valve" that is "acted upon by a pressure of at least a threshold magnitude" must be a valve that operates due to fluid pressure applied to the valve. (App. Br. 6:17-23.) According to Boston Scientific, its specification describes only flow pressure from a fluid as the means to open its valve and does not describe the use any other pressure, such as manual

pressure. (*Id.* at 6:23-7:9.) Boston Scientific concludes that Mikhail's valve which opens due to manual pressure applied to the valve membrane is not a "pressure actuated valve" with a membrane that is "acted upon by a pressure" as recited in claim 1.

Boston Scientific's argument is not persuasive. Boston Scientific's specification does not define the term "pressure" as meaning only fluid pressure or flow pressure. During examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Hyatt*, 211 F.3d at 1372. Absent claim language carrying a narrow meaning, a claim should only be limited based on the specification and prosecution history when those sources expressly disclaim the broader definition. *In re Bigio*, 381 F.3d at 1325.

Boston Scientific does not direct us to any portion of its specification or prosecution history that expressly disclaims applying pressure to the sides of its valve. Simply because Boston Scientific's specification describes the use of flow pressure to open a valve does not mean that using other types of pressure is excluded. Note that there is no requirement in patent law for an applicant to specifically describe in its specification every single embodiment falling within the scope of a claim. The Examiner's interpretation of "pressure" as broadly including both flow pressure and manual squeezing pressure is neither unreasonable nor inconsistent with Boston Scientific's specification.

Moreover, the broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an

amendment. *In re Bigio*, 381 F.3d at 1324. If Boston Scientific intended that the valve of claim 1 open only due to fluid or flow pressure it could easily have used the term “fluid pressure” or “flow pressure” in the claim as it did, for example in claims 20 and 21, but it did not. We reject the argument that the term “pressure” in claim 1 must only mean “fluid pressure” or “flow pressure.”

In the alternative, the Examiner also found that even if claim 1 does require that the valve open due to fluid flow pressure, an inherent feature of Mikhail’s valve is that the slits in the valve membrane will open if subjected to a flow pressure of sufficient magnitude. (Ans. 6:19-7:9.)

Boston Scientific argues that Mikhail intends only that its valve be opened by manual squeezing pressure exerted on the sides of the valve and does not contemplate opening of the valve due to fluid pressure. (App. Br. 7:10-14; Reply Br. 4:7-17.) According to Boston Scientific, if Mikhail’s valve were opened by fluid pressure, that would represent failure of the valve. (App. Br. 8:4-7; Reply Br. 4:17-20.) Boston Scientific thus contends that Mikhail does not disclose a valve that opens in response to fluid pressure.

We reject Boston Scientific’s contention. A prior art reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect. *EWP Corp.*, 755 F.2d at 907; *see also In re Bode*, 550 F.2d at 661. Mikhail opens its valve by applying squeezing pressure from the sides of the valve and does not rely on fluid pressure to open the valve. Any “failure” due to opening by fluid pressure is only in the context of the particular use and intended purpose disclosed in Mikhail. Boston Scientific’s claims are not

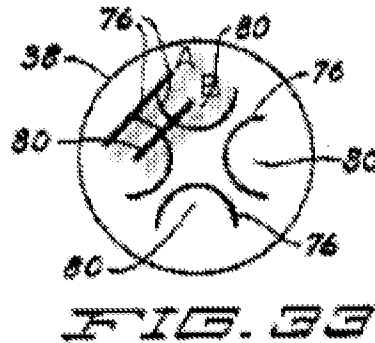
limited to that use. Thus, opening the valve by fluid pressure cannot be deemed a failure in the context of Boston Scientific's claimed invention.

Boston Scientific also contends that there is no reason to assume that Mikhail's valve would successfully open in response to a fluid pressure of a threshold magnitude. (App. Br. 7:14-16.) The rationale for that contention is simply that Mikhail does not disclose the use of fluid pressure to open its valve. Boston Scientific, however, overlooks what Mikhail inherently discloses. Mikhail's Figure 16 shows an embodiment of Mikhail's valve 36 in which openings or slits 76 of valve member 38 have been forced open due to the insertion of stent tube 88. (Mikhail 23:54-65.) Thus, Mikhail discloses that a pressure of sufficient magnitude caused by the insertion of the stent tube will force open the slits of the valve. That is evidence indicating that the valve would also open when it is subjected to a fluid pressure of sufficient magnitude. Boston Scientific does not explain why Mikhail's valve would not open in response to fluid pressure as it would due to pressure from the stent tube. We agree with the Examiner's finding that the valve disclosed in Mikhail has slits that would open in response to fluid pressure of a sufficient threshold magnitude.

Boston Scientific further argues that Mikhail does not disclose that "a distance between a first end portion of a first one of the slits and a first end portion of second one of the slits is a minimum distance between the first and second slits[.]" as required by claim 1. (App. Br. 9:1-6.)

In accounting for that requirement, the Examiner stated that: "the examiner is defining the 'end portions' of the slits as the area between points A and B in the figure shown below, at point B of the end portion is smallest distance between the two slits." (Ans. 4:1-3.)

The figure referenced by the Examiner is an annotated copy of Mikhail's Figure 33 which is reproduced below (Ans. p. 4):



The figure depicts a diagrammatic view of Mikhail's valve.

Thus, the Examiner determined that an "end portion" of a slit in Mikhail includes a segment of the slit that extends inwardly from the terminal end of the slit.

Boston Scientific argues that the Examiner's definition of the end portions of Mikhail's slits is improper. Boston Scientific states (Reply Br. 6:15-19):

an end of a slit is defined as "the portion of an area or territory that lies at or by the termination and that often serves as a delimitation or boundary." (See definition, Webster's Third New International Dictionary). It is therefore evident that the end portion can not comprise a center portion of the slit, as the center portion does not lie by the termination point thereof.

Boston Scientific's argument is unpersuasive. Boston Scientific's specification does not define the "end portion" of a slit to mean only the single endmost "point" of the slit. Neither does Boston Scientific's above-quoted definition limit the "end" or "end portion" of a slit solely to the terminal point. As determined by the Examiner, the "end portion" of Mikhail's slit is a small end section of the slit that includes the terminal

point of the slit. As is shown in the annotated Figure 33 above, the end portion of each slit extends only partially towards the center but does not reach the center. The Examiner's determination that the end portions of Mikhail's slits include sections that extend inwardly from the endmost points of the slits is reasonable.

Boston Scientific's claims require only that "*a* distance" between end portions of adjacent slits is a minimum distance. As correctly determined by the Examiner, the distance between the slits at the line marked "B" in the annotated copy of Mikhail's Figure 33 reproduced above is a minimum distance between two adjacent slits. We reject Boston Scientific's argument that Mikhail does not disclose a distance between an end portion of a first slit and an end portion of a second slit that is a minimum distance between the slits as required by claim 1.

For the foregoing reasons, we sustain the rejection of claims 1-9 and 17-21.

Claims 10-16

Dependent claims 11-16 are argued collectively with independent claim 10. Claim 10 is drawn to a flow control device for a pressure actuated valve. Claim 10 requires a "substantially planar elastic membrane...." Boston Scientific disputes that Mikhail discloses a membrane that is substantially planar.

The Examiner states that: "[t]he examiner is interpreting 'substantially planar' to mean substantially lying in a plane, which the membrane (38) certainly does." (Ans. 4:15-5:1.) Thus, according to the Examiner, Mikhail's valve membrane 38 meets the "substantially planar" requirement of claim 10.

The ordinary meaning of “planar” is “flat.” *Webster’s II New Riverside University Dictionary* 898 (1984). That meaning is recognized in the art as evidenced by Mikhail’s disclosure which equates the term “planar” with the terms “generally flat” and “completely flat.” (Mikhail 24: ll. 46 and 56.) Thus, “substantially planar” means substantially flat. Mikhail discloses member 38 as being arcuate or dome shaped. (Mikhail 11:12-13; 23:27-28.) The Examiner does not explain how the arcuate or dome shape of Mikhail’s valve member 38 is also a substantially flat shape.

We do not sustain the rejection of claims 10-16 as anticipated by Mikhail.

F. CONCLUSION

1. Boston Scientific has not shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane that is acted upon by a pressure of at least a threshold magnitude.

2. Boston Scientific has not shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane with slits where a distance between an end portion of a first slit and an end portion of a second slit is a minimum distance between the slits.

3. Boston Scientific has shown that the Examiner was incorrect in finding that Mikhail discloses a valve membrane that is substantially planar.

G. ORDER

The rejection of claims 1-9 and 17-21 under 35 U.S.C. § 102(b) as anticipated by Mikhail is affirmed.

The rejection of claims 10-16 under 35 U.S.C. § 102(b) as anticipated by Mikhail is reversed.

Appeal 2009-003237
Application 10/768,565

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

MAT

Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038